DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 16, 2014

Boston Scientific Corporation
Mr. Thomas Hirte
Senior Regulatory Affairs Manager
100 Boston Scientific Way
Marlborough, MA 01752

Re: K141584
Trade/Device Name: Ultraflex™ Tracheobronchial Partially Covered Stent System
Regulation Number: 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: Class II
Product Code: JCT
Dated: September 12, 2014
Received: September 15, 2014

Dear Mr. Hirte,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K141584**

Device Name: Ultraflex™ Tracheobronchial Stent System

Indications for Use: The Ultraflex™ Tracheobronchial Stent System is intended for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4560
Fax: 508-683-5939

Contact: Thomas Hirte
Senior Regulatory Affairs Manager
Date Prepared: June 18, 2014

Secondary Contact: Ashley Santos
Senior Regulatory Affairs Manager
Date Prepare: June 18, 2014

2. Proposed Device:

Trade Name: Ultraflex™ Tracheobronchial Partially Covered Stent System
Classification Name: Tracheal Prosthesis
Regulation Number: 878.3720
Product Code: JCT
Classification: Class II

3. Predicate Device:

Trade Name: Ultraflex™ Tracheobronchial Uncovered Stent System
Manufacturer and Clearance Number: Boston Scientific Corporation, K121048
Classification Name: Tracheal Prosthesis
Regulation Number: 878.3720
Product Code: JCT
Classification: Class II

Trade Name: Aero Tracheobronchial Stent Technology System
Manufacturer and Clearance Number:Alveolus Inc. (Merit Medical Endotek), K082284
Classification Name: Tracheal Prosthesis
Regulation Number: 878.3720
Product Code: JCT
Classification: Class II

4. Proposed Device Description:

The Ultraflex Tracheobronchial Stent Systems are permanently implanted expandable metal stents designed to serve as an intralumenal support to keep open the inner lumen of the tracheobronchial tree. They consist of a flexible delivery catheter preloaded with an expandable metallic stent.

The stent is an open-ended cylindrical mesh constructed from a single strand of nitinol wire. The wire is configured into a series of circumferential interwoven loops, with the number of loops being dependent

on the diameter of the stent. The stent is elongated and compressed onto a plastic delivery catheter. The stent is held onto the delivery catheter by a crocheted nylon suture wrapped around the stent. The delivery catheter has a flush taper tip at the distal end, and a round hub handle at the proximal end.

The covered stent has a single layer of translucent polyurethane that covers the midsection of the stent.

Covered stents are available with a distal release system only. The distal release system begins stent deployment from the lower (distal) end of the delivery catheter.

The radiopaque (RO) markers on the delivery system and stent facilitate fluoroscopic placement.

The covered stent has four RO markers. The outer two (2) RO markers indicate the estimated final position of the ends of the deployed stent. The inner two (2) RO markers indicate the estimated final position of the margins of the deployed stent cover (Figure 1B).

The delivery system accepts a 0.035 in (0.89 mm) or 0.038 in (0.97 mm) guidewire. The delivery system is passed over the guidewire into the tracheobronchial lumen. The stent is positioned appropriately using the RO markers for guidance under fluoroscopy and by bronchoscopic visualization of the stent.

The stent is deployed by holding the handle hub in the palm of one hand, and grasping the finger ring with the other hand. By retracting the finger ring the suture crochet knots are unraveled in a circular manner along the length of the stent, gradually deploying the stent. When using the proximal release system, stent deployment begins from the upper (proximal) end of the delivery system, and continues to release toward the tip of the delivery system (distally) as the entire suture unravels. When using the distal release system, stent deployment begins from the lower (distal) end of delivery system, and continues to release towards the operator (proximally) as the entire suture unravels.

After the stent is completely released, and the nylon suture has been completely removed, the delivery system catheter can be removed.

5. Indications for Use:

The Ultraflex™ Tracheobronchial Stent System is intended for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

6. Technological Characteristics:

The proposed Ultraflex Tracheobronchial Partially Covered Stent System is a new configuration of the product, which has a silicone cover applied to the stent. The material of the proposed silicone cover used on the Ultraflex Tracheobronchial Partially Covered Stent System is identical to the silicone cover material used on the Wallflex Esophageal Fully Covered Stent System cleared per K091510. With the exception of the silicone cover, the proposed Ultraflex™ Tracheobronchial Partially Covered Stent System is identical in design, materials, and intended use to the currently cleared Ultraflex™ Tracheobronchial Uncovered Stent System (K121048).

7. Performance Data:
In-vitro testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests. This 510(k) notification contains physical test results for the Ultraflex Tracheobronchial Partially Covered Stent System as specified in the FDA "Guidance for the Content of Premarket Notifiatiosn for Esopaheal and Tracheal Prosthesis" document (April 28, 1998) and as requested by the FDA during the FDA review of K101384 and K121048. Testing included but was not limited to: Dimensional, fatigue, compression, expansion, deployment accuracy, magnetic resonance, corrosion, sterility, pyrogenicity, and biocompatibility.

Sterilization was performed using Ethylene Oxide according ANSI/AAMI 11135-1:2007 with a Sterility Assurance Level of 10^{-6}. Sterilization residuals comply with ANSI/AAMI 10993-7:2012.

Biocompatibility testing was confirmed via AAMI/ANSI/ISO 10993-1:2009.

No detectable endotoxin was confirmed via Pyrogen testing conducted according to AAMI ST72 and USP 85 and USP 161.

Magnetic Resonance testing was confirmed via ASTM F2503-13, ASTM F2119-07, ASTM 2213-06, and ASTM 2052-06.

8. Conclusion:
Boston Scientific Corporation has demonstrated that the proposed Ultraflex™ Tracheobronchial Partially Covered Stent System is substantially equivalent to Boston Scientific Corporation's currently marketed Ultraflex Tracheobronchial Uncovered Stent System (K121048), Merit Aero Tracheobronchial Stent Technology System (K082284), and the Wallflex Esophageal Fully Covered Stent System (K091510).